

### **REMARKS**

The Office Action dated December 12, 2006 has been carefully considered. Claims 1-33 are pending in the present application. Claims 6, 7, 16, and 20 have been withdrawn by the Examiner. In the Office Action, the Examiner indicates that claims 27-33 are allowed.

Reconsideration of the present application in view of the following remarks is respectfully requested.

#### **I. CLAIM REJECTION UNDER 35 U.S.C. § 102(b)**

Claims 1-5, 8, 15, and 17-19 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,693,029 to Leonhardt ("Leonhardt"). Applicants respectfully disagree.

Independent claim 1 is directed to an apparatus for delivering a biologically active material to a body lumen comprising a catheter, a balloon having an outer surface and an interior compartment for containing the biologically active material, and a plurality of micro-needles disposed upon the outer surface of the balloon, wherein the micro-needles are capable of being ruptured and capable of contacting the body lumen to deliver the biologically active material to the body lumen. Claims 2-5 and 8 depend from claim 1 and, thus, also include these recitations.

Independent claim 15 is directed to an apparatus for delivering a biologically active material to a body lumen, comprising a catheter, a balloon having an outer surface and an interior compartment for containing the biologically active material, and a plurality of micro-needles disposed upon the outer surface of the balloon, wherein the micro-needles each have a lumen in fluid communication with the interior compartment, and are capable of contacting the body lumen to deliver the biologically active material from the interior compartment through the lumens of the micro-needles to the body lumen. Claims 17-19 depend from claim 15 and, thus, also include these recitations.

Leonhardt does not teach or suggest a *balloon having an interior compartment for containing the biologically active material* as recited in the present claims. Leonhardt discloses a flexible and kink-proof intra-cavity catheter for injection of a therapeutic agent into the wall of a body cavity. (*See Abstract*). As shown in Figure 1 of Leonhardt, the catheter 10 of Leonhardt has an angioplasty or distal balloon 16 at the end of a catheter body 12 and a flexible and expandable invention site 18. (Col. 3, lines 57-60). Figure 2 of Leonhardt shows the invention site 18 including a distal balloon inflation lumen 20, an

internal balloon inflation lumen 22, one or more retraction members 26, one or more needle assemblies 24 which include hollow shafts 30 and a plurality of needles 32, and an internal inflation balloon 28. (Col. 4, lines 4-21). The internal inflation balloon 28 is inflated when an expansion agent is introduced through the internal balloon inflation lumen 22. (Col. 4, lines 63-65). When the internal inflation balloon 28 is inflated, the needle assemblies 24 with the needles 32 are pushed out of the catheter towards the tissue of the body cavity wall. The needles 32 can be extended into or through the cavity wall. A therapeutic agent is delivered to the cavity wall through the hollow shafts 30 and needles 32. (Col. 4, line 20 to col. 5, line 13). In contrast to the claimed invention, the internal inflation balloon of Leonhardt is not a balloon having an interior compartment for containing the biologically active material.

Because Leonhardt does not teach or suggest a balloon having an interior compartment for containing the biologically active material, Leonhardt also does not disclose or suggest a plurality of micro-needles disposed on the outer surface of a balloon having an interior compartment for containing the biologically active material as recited in the present claims.

Moreover, Leonhardt does not disclose or suggest a plurality of micro-needles. Leonhardt's needles are not micro-needles. In fact, Leonhardt teaches away from using micro-needles in a number of statements that indicate that the needles of the catheter in Leonhardt are not micro-needles.

For example, Leonhardt states that the needles of its catheter can become stuck in the tissue of the body cavity wall. To prevent this, retraction members 26 are included in the catheters in Leonhardt to pull the needles back into the catheter. (Col. 5, line 14-25). Because of their small diameter and length, micro-needles, even when their entire length pierces the body cavity wall tissue, would not become stuck in the body cavity wall tissue. Once the balloon is deflated, the micro-needles should readily disengage the cavity wall tissue. Therefore, by stating that its needles can become stuck in the body cavity wall tissue, Leonhardt indicates that its needles are not micro-needles but are instead needles having substantially larger diameters and lengths.

In addition, Leonhardt indicates that in one embodiment each end of the retraction members 26 are placed "around a tissue insertion needle" of different needle assemblies. (Col. 5, lines 25-29). Leonhardt also discloses that the retraction members 26 are made of an elastic material, such as "a rubber band" or a "locking ring". (Col. 5, lines 22-25). One of ordinary skill in the art would recognize that it would not be possible to place a rubber band

around a micro-needle so that the rubber band can function as a retraction member described in Leonhardt. More specifically, as discussed in Leonhardt and shown in Figure 2 thereof, in order for the retraction members or rubber bands 26 to exert a force in opposition to the outward pressure of the balloon 28 to prevent the needles in Leonhardt from being stuck in the cavity wall tissue, one end of each rubber band is placed or anchored around a single needle. (Col. 5, lines 22-29). Because of their small length of at most 1 mm, a micro-needle would not provide enough area onto which a rubber band can be placed or anchored. In addition, because of their small diameter, micro-needles would not be stiff enough to support the rubber bands. Also, because of the density of micro-needles on the outer surface of balloon, it would be difficult to place a rubber band around a single micro-needle. Therefore, in order for the needles described in Leonhardt to anchor or support the ends of the retraction members or rubber bands, the needles cannot be micro-needles.

For the foregoing reasons, Leonhardt does not teach or suggest a balloon having an interior compartment for containing the biologically active material and a plurality of micro-needles disposed on the outer surface of such balloon as recited in claims 1 and 15 and their dependent claims.

Since Leonhardt fails to teach each and every element of the claims, it is believed that claims 1 and 15 and the claims depending therefrom are patentable over Leonhardt. Accordingly, Applicants respectfully request withdrawal of this rejection and allowance of claims 1-5, 8, 15, and 17-19.

## **II. CLAIM REJECTION UNDER 35 U.S.C. § 103(a)**

Claims 9-14, and 21-26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leonhardt in view of U.S. Patent No. 6,565,532 to Yuzhakov *et al.* ("Yuzhakov"). Applicants respectfully disagree.

A finding of obviousness requires that the prior art both suggest the invention and provide one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Further, in order for the cited references to be combined together to render the claimed invention unpatentable, the references must provide some suggestion, motivation, or teaching to make the combination. *Northern Telecom, Inc. v. Datapoint, Corp.*, 908 F.2d 931, 934 (Fed. Cir. 1990) (It is insufficient that the prior art separately discloses the components of the claimed invention).

Claims 9-14 depend from claim 1 and further recite that the micro-needles have certain specific physical characteristics, *e.g.*, diameter (claim 9), length (claims 10-12), and density (13-14). Claims 21-26 depend from claim 15 and also further recite that the micro-needles in the apparatus of claim 15 have certain specific physical characteristics, *e.g.*, diameter (claim 21), length (claims 22-24), and density (25-26). As discussed above, claims 1 and 15 are patentable over Leonhardt. Thus, claims 9-14 and 21-26, which depend from claims 1 and 15, respectively, are also believed to be patentable over Leonhardt for the reasons discussed above in connection with claims 1 and 15. In particular, Leonhardt does not disclose or suggest a balloon having an interior compartment for containing the biologically active material and a plurality of micro-needles disposed on the outer surface of such balloon as recited in claims 1 and 15. In addition, Leonhardt teaches away from the use of micro-needles.

Yuzhakov does not remedy the deficiencies of Leonhardt. Yuzhakov does even not disclose or suggest the use of a catheter or a balloon. Instead, Yuzhakov is directed to the use of an array of micro-needles to apply semi-permanent or permanent markings to skin, or to apply semi-permanent subcutaneous makeup or other cosmetic compounds to skin and, thus, relates to a technical field that is different from the present invention and the apparatus of Leonhardt. (*See Abstract*). Thus, one of ordinary skill in the art would find no motivation to modify or combine the teachings of Leonhardt and Yuzhakov to obtain the presently-claimed apparatus. Moreover, because Leonhardt indicates that the needles employed in the catheter are not micro-needles, as discussed above, Applicants further submit that an ordinary artisan would not have a reasonable expectation of success in combining the teachings of Leonhardt and Yuzhakov to obtain the present invention.

Furthermore, since Yuzhakov does not disclose or suggest that its array of micro-needles includes a catheter or balloon, Yuzhakov does not teach or suggest an apparatus for delivering a biologically active material to a body lumen comprising a catheter as well as a balloon having an outer surface and an interior compartment for containing the biologically active material, and a plurality of micro-needles disposed upon the outer surface of the balloon and capable of contacting the body lumen to deliver the biologically active material to the body lumen, as recited by claims 1 and 15. Moreover, Yuzhakov does not teach or suggest an apparatus having the above elements that further has the specific physical characteristics of the micro-needles as recited in claims 9-14 and 21-26.

For the above reasons, claims 9-14 and 21-26, which depend from claims 1 and 15, respectively, are believed to be patentable over Leonhardt and Yuzhakov. As such, withdrawal of this rejection and allowance of claims 9-14 and 21-26 are respectfully requested.

**III. ALLOWABLE SUBJECT MATTER**

As indicated in the Office Action, claims 27-33 are allowed.

**IV. CONCLUSION**

As the Examiner's rejections have been overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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